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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/687,297	10/16/2003	Jerzy Olejnik	AMBER-07185	7926
7590 11/02/2005			EXAMINER	
Peter G. Carroll MEDLEN & CARROLL, LLP Suite 350 101 Howard Street San Francisco, CA 94105			CHUNG, SUSANNAH L	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/687,297

Applicant(s)

OLEJNIK ET AL.

Examiner

Susannah Chung

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 July 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-53 is/are pending in the application.
- 4a) Of the above claim(s) 1-19 and 31-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 20-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

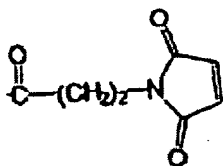
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DETAILED ACTION

Claims 1-53 are pending in the instant application.

Response to Election/Restrictions

Applicant's election *without traverse* of Group III, Claims 20-30, in the reply filed on 07/08/2005 is acknowledged. Specially, the election of the "PRG" (Protein Reactive Group) as the



compound of the following structure:

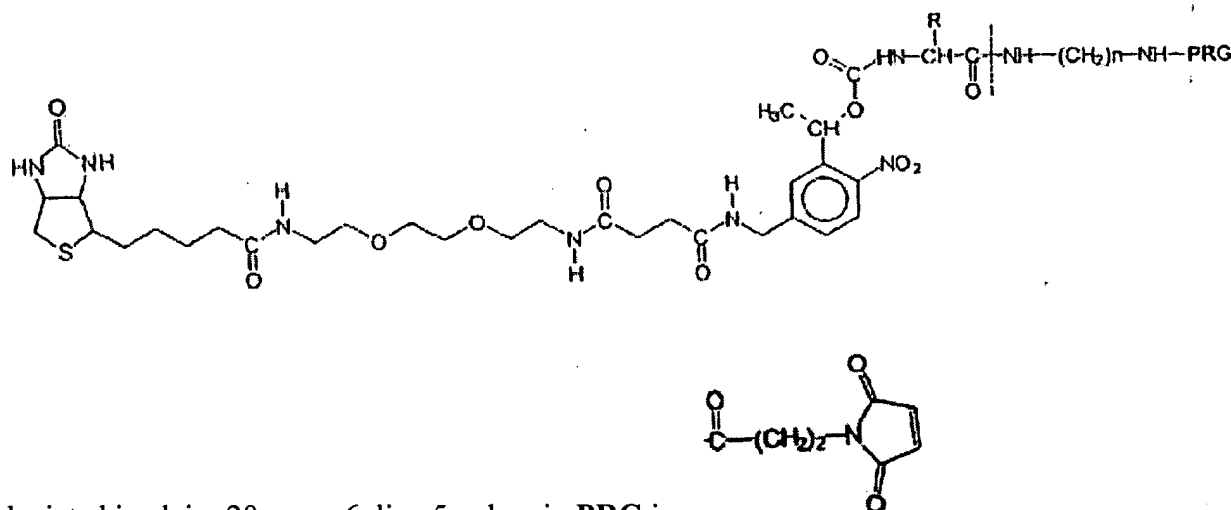
Scope of the Elected Invention

Claims 1-53 are pending in this application. Claims 1-19 and 31-53 are withdrawn from further consideration by the examiner, 37 C.F.R. §1.142(b), as being drawn to a non-elected invention. The withdrawn subject matter is patentably distinct from the elected subject matter as it differs in structure and element and would require separate search considerations. In addition, a reference, which anticipates one group, would not render obvious the other.

The scope of the elected subject matter that will be examined and searched is as follows:

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Compounds of the general formula,

depicted in claim 20, page 6, line 5, wherein **PRG** is***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

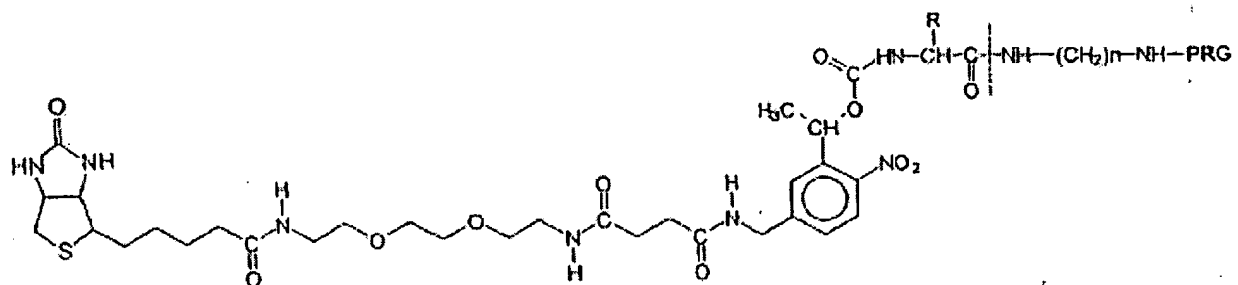
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

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Claims 20-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Huber et al., (U.S. Patent No. 5,219,764) in view of Pandori et al., Chemistry & Biology, Vol. 9, 567-573, May 2002.

Applicants instant elected invention teaches a photocleavable compound having the general formula:



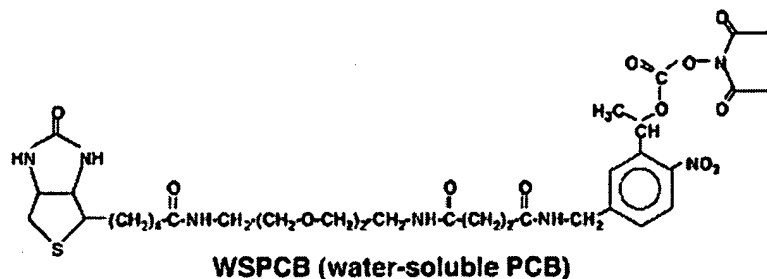
depicted in claim 20, wherein R is an aliphatic hydrocarbon chain; wherein the portion defined by –HN-CHR-CO– comprises one or more stable isotopes; and PRG is a protein reactive group that reacts with functional groups on proteins. These compounds are photocleavable and are used for studying receptors and delivery of gene-transfer agents.

Determination of the scope and content of the prior art (MPEP § 2141.01)

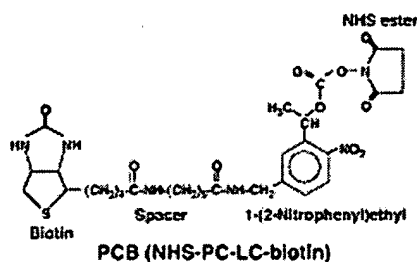
Huber teaches a hapten-biotin conjugate consisting of a hapten linked to biotin via a spacer having a chain of from 30 to 36 atoms at least five of which are the heteroatoms selected from the group consisting of nitrogen, oxygen and combinations thereof.

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Pandori teaches photocleavable biotinylation reagents of formula,



and



, Biotin-Spacer-1-(2-Nitrophenyl)ethyl-NHS ester, as taught in

Figure 1, page 568, Compound A. These photocleavable compounds are used for controlling the infectivity of adenoviral vectors. This strategy involves a method whereby the infectivity of adenoviral vectors is neutralized by treatment of viral particles with a water-soluble, photocleavable biotinylation reagent.

Ascertainment of the difference between the prior art and the claims (MPEP § 2141.02)

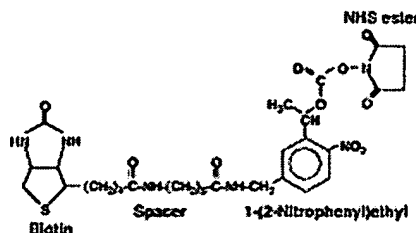
The difference between the prior art of Huber and the claims is that the instant application is more specific than the prior art.

Both the prior art of Pandori and the instant application have the same core structure that of Biotin-Spacer-1-(2-Nitrophenyl)ethyl-NHS ester. The difference between the prior art of Pandori and the claims is that the structure of the last fragment, the NHS ester is different.

Finding of prima facie obviousness – rationale and motivation (MPEP § 2142-2413)

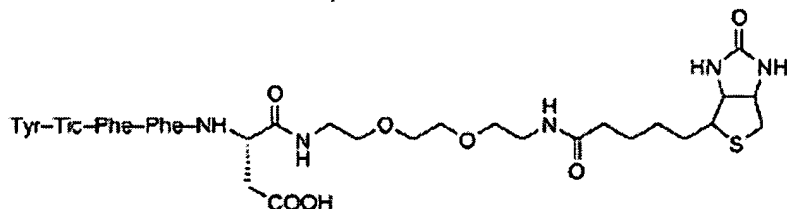
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One skilled in the art would have found the claimed compound *prima facie* obvious in light of Huber in view of Pandori's teaching because the instantly claimed compound and the compound in Huber and Pandori have the same core structure, that of Biotin-Spacer-1-(2-Nitrophenyl)ethyl-



NHS ester, as taught in Figure 1, page 568,

The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (i.e. pharmacological use). Both the instantly claimed compounds and the compounds of Huber and Pandori are used as photocleavable compounds. In addition, the prior art of Kumar teaches photocleavable compounds of formula,



, as taught in Scheme 1, page 615,

Compound 2. These photocleavable compounds are peptide derivatives containing a biotin or a fluorescent label can be useful pharmacological tools for studying receptors. Biotinylated peptides, such as the compounds in the instant application, can be used in receptor purification and fluorescently labeled ligands can also be used for studying receptor localization and internalization. Kumar teaches that this general synthetic scheme could be used to attach different labels such as

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biotin or a fluorescent group via a hydrophilic spacer to lead peptides or in the instant case, an NHS ester. (See Kumar et al., Organic Letters, Vol. 5, No. 5, pp. 613-616, October 7, 2002).

Although, applicant's compound differs in that the prior art of Huber is more general, the instant claims read on Huber when read in light of Pandori. In addition, they are used for the same pharmacological use so one skilled in the art would expect the species would have similar properties as the genus.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 20-30 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The terms "aliphatic hydrocarbon chain," "PRG," "protein reactive group," "isotopes," "sulfhydryl reactive group," "amine reactive group," are not described in the specification, claims or drawings. Applicant is invited to point out where in the original specification, claims or drawings the terms are defined. If a proper definition cannot be found, then applicant may obviate this rejection by deleting the terms from the claims.

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Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susannah Lee whose telephone number is (571) 272-6098. The examiner can normally be reached on M-F, 8am-5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph McKane can be reached on (571) 272-0699. The fax phone number for the organization where this application or proceeding is assigned is (571) 272-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Susannah Lee
Patent Examiner, AU 1626
Date: 10/29/05

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

Kamal Saeed